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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/538,916 | 06/13/2005 | Fumio Nomura | 050337 | 8854 |
| 23850 7590 08/19/2008 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005 | | | | |
| EXAMINER | | | | |
| ROOKE, AGNIS BEATA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1656 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,916

Applicant(s)

NOMURA ET AL.

Examiner

AGNES B. ROOKE

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 17 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 17 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/CIS)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This FINAL office action is in response to the paper filed on 05/02/2008.

The amendments to the claims are acknowledged.

Status of Claims

Claims 1 and 17 are pending and under consideration. Claims 2-16 and 18-21 are cancelled.

Objections and Rejection Withdrawn

The objection of claims 1, 2, and 17 is withdrawn in view of the amendments to the claims and cancellation of the claims.

The objection to specification is withdrawn in view of the amendments.

The rejection of claims 1, 2, 5, 6, and 17 under 35 USC 101 is withdrawn in view of the amendments to the claim sand cancellation of the claims.

The rejection of claims 1, 2, 5, 6, and 17 under 35 USC 112, second paragraph, is withdrawn in view of the amendments to the claims and cancellation of the claims.

The rejection of claims 1, 2, 5, 6, and 17 under 35 USC, first paragraph, written description, is withdrawn in view of the amendments to the claims and cancellation of the claims.

The rejection of claims 1, 2, 5, 6, and 17 under 35 USC, first paragraph, scope of enablement, is withdrawn in view of the amendments to the claims and cancellation of the claims.

Rejection Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Garner et al. (U.S. 5,639,940).

Garner et al. teach in columns 25-30, the amino acid sequence that has 644 amino acids that comprises the instant SEQ ID NO:1. (See columns 25-30 in reference to the instant amino acids 576-629 specifically).

Claims 1 and 17 are rejected because they claim a protein having SEQ ID NO:1 (claim 1), which includes any protein having SEQ ID NO:1 embedded in it, and Garner et al. teach a sequence that comprises SEQ ID NO:1 (claim 17).

Applicants responded that Garner et al. do not teach isolation of SEQ ID NO:1, and that SEQ ID NO:1 is not identified as being useful for diagnosis of liver disease. Further, Applicants state that Garner et al. describes production of fibrinogen in transgenic animals using the amino acid sequence that contains the instant SEQ ID NO:1.

Examiner responds that the instant claims refer to a polypeptide that comprises SEQ ID NO:1, that is can contain embedded within it, and the instant polypeptide does not consist of SEQ ID NO:1, that is exactly and only SEQ ID NO:1, thus any peptide that

contains SEQ ID NO:1 would anticipate the instant claims. Further, Garner et al. teach in claim 12 in column 77 last sentence, that the fibrinogen is recovered from the milk, thus the fibrinogen containing SEQ ID NO:1 is isolated. Moreover, using the marker-protein for diagnosing the liver disease represents an intended use that does not materially affect the product being claimed. Therefore, the rejection is proper and is thus maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-273-0931. The fax phone

Art Unit: 1656

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

/Kathleen Kerr Bragdon/

Supervisory Patent Examiner, Art Unit 1656